510(k) SUMMARY

Submitter Information

Submitter's Name:	OrthoHelix Surgical Designs, Inc.
Address:	1065 Medina Rd, Suite 500 Medina, Ohio 44256
Telephone Number:	330-869-9562
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Prepared By:	Liz Altenau, Brian Hockett, and Caitlin Miller
Contact Person:	Brian Hockett or Derek Lewis
Date Prepared:	3/13/2013

AUG 15 2013

Device Information

Trade Name:	OrthoHelix™ Staple System
Common Name:	Bone Staple
Classification Name:	Staple, Fixation, Bone
Device Classification:	Single/multiple component metallic bone fixation appliances and accessories Class II per 21 CFR 888.3030 Panel: Orthopedic, Product Code: JDR
Material Composition:	Nickel Titanium Alloy
Device Description:	The OrthoHelix™ Staple System consists of various sizes of staples used for fixation in the hand and foot. The staples are offered in different lengths, widths, and thicknesses. All implantable devices within this system are manufactured from shape memory nickel titanium alloy.
Intended Use:	The OrthoHelix™ Staple System is indicated for fixation in the hand and foot including fractures, fusions, and osteotomies.
Substantial Equivalence:	The new OrthoHelix™ staples are substantially equivalent to the Stryker (Memometal Technologies) EasyClip Staple (K070031) and the BioMedical Enterprises Inc. Speed Staple (K993714). The OrthoHelix™ Staple System conforms to ASTM F2063 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical implants. Engineering calculations, finite element analysis, mechanical bending and pullout tests per ASTM F564, and corrosion testing per ASTMF2129 were performed to demonstrate substantial equivalence of the subject to the predicate devices. No new issues of safety and effectiveness have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 15, 2013

OrthoHelix Surgical Designs, Incorporated
% Mr. Brian Hockett
Portfolio Manager
1065 Medina Road, Suite 500
Medina, Ohio 44256

Re: K130832
Trade/Device Name: OrthoHelix™ Staple System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: July 2, 2013
Received: July 3, 2013

Dear Mr. Hockett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin L. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130832

Device Name: OrthoHelix™ Staple System

Indications for Use:
The OrthoHelix™ Staple System is indicated for fixation in the hand and foot including fractures, fusions, and osteotomies.

Prescription Use ___X___ AND/OR Over-The-Counter-Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices